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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,221	08/20/2001	Paul Jarrett	0380-P02546USO	6745
110	7590	10/09/2003	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/856,221	JARRETT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3 and 53-68 is/are pending in the application.
- 4a) Of the above claim(s) 59-62, 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 53-56 and 63-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. Applicants' amendment and response filed July 15, 2003 as Paper Number 10 to Office Action mailed March 11, 2003 as paper Number 9, and Supplementary response filed September 11, 2003 are acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. Claims 3, 53-56, and 59-68 are pending.

### ***Election/Restrictions***

3. Claims 3, 53-56 and 63-66 stand elected. Originally presented Claims 59 and 61, previously added Claims 67, 68 and currently amended Claims 60 and 62, directed to inventions that is independent or distinct from the invention originally claimed stand non-elected for the following reasons: Said claims are drawn to a composition different than that claimed in Claims 3, 53-56 and 63-66 and to a non-elected invention as indicated in applicants' response filed November 21, 2002 as Paper Number 8. Claims 59-62 and 67-68 have consequently been withdrawn from further consideration for the reasons of record on pages 2-3 of the Office action mailed March 11, 2003 as Paper Number 9.
4. In response to this rejection and withdrawal of Claims 59-62 and 67-68, citing the M.P. E. P. 1893.03(d) and Example 17 of Annex B Part 2 of said M.P.E.P. citation, applicants argue that Examiner's restriction requirement in Office Action mailed October 10, 2002 as Paper Number 7 "is plainly unjustified", "contravenes well-established U. S. Patent and Trademark Office practice regarding the proper implementation of the PCT's Unity of Invention standards and fails to comply with Standard U.S. PTO guidance. Applicants further demand a citation of relevant authority that warrants a lack of unity consideration among different inventions encompassed by inventions in Groups I-IV, especially Groups I and III-IV. Applicants further argue that during the International stage prosecution of said application all original claims were considered as a single invention

In response to applicants' above referred arguments, first of all applicants affirm on record at Page 2 of the remarks of response filed July 15, 2003 as Paper Number 10 that the claim language "a protein and the DNA sequence encoding it exhibits corresponding special technical features, satisfies the PCT's unity of inventive requirement. In contrast this application is now being prosecuted under U.S. National Stage regulations. Furthermore, in Example 17 of Annex B, Part 2 of above-cited M.P.E.P. citation, unity of invention is said to occur because the protein X and the DNA sequence encoding said protein X share a corresponding technical feature, protein X. The claims in said example are:

1. Protein X.
2. DNA encoding protein X.

However, in the instantly claimed invention, Claim 53 is drawn to functionally defined proteins, not specific proteins X having specific sequences, while Claim 59 is drawn to no specific DNAs having no specific sequences either. Thus, there is no corresponding technical feature of protein X that the two claims share.

Moreover, the restriction requirement on instant application has already been made Final. Therefore, now said restriction requirement is a petitionable matter.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-62 and 67-68 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. A complete reply to the final rejection **must** include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's arguments filed July 15, 2003 as Paper Number 10 have been fully considered but they are not persuasive. The Restriction Requirement made Final in Office Action mailed March 11, 2003 as paper Number 9 is therefore, adhered to for the reasons of record in Office actions mailed October 10, 2002 as Paper Number 7 and on March 11, 2003 as paper Number 9.

5. Claims 3, 53-56 and 63-66 are examined on merits.

### ***Claim Rejections - 35 U.S.C. § 112***

6. Currently amended Claims 64 and 66 stand rejected under 35 U.S.C. § 112, first paragraph.

In response to this rejection, applicants argue that the "enablement provided by the specification is commensurate with the scope of applicants' claimed invention according to currently amended Claims.

In response to applicants' above-cited arguments, currently amended Claims 64 and 66 still remain non-enabled because the specification, while enabling for a method to identify the homology of said nucleotides to Seq. I.D. 1-4, fails the Wand test because mere 70% homology is not enabling for encoding the same protein or agent that has the same insecticidal activity as claimed. Moreover, applicants have not recited which of the sequences is a derivative of which one or all of SEQ. I.D. 1-4 or which of the one or more nucleotide (s) have been added, inserted, deleted or substituted or whether only one or more than one nucleotide have been altered, because anyone, or all of said manipulations in the nucleotide sequence of said DNA molecule may result in a protein with an entirely different activity/property than the one claimed in the instant invention.

Applicant's arguments filed July 15, 2003 as Paper Number 10 with regard to above rejections have been fully considered but they are not persuasive. The rejection under 35 U.S.C. § 112, first paragraph to amended Claims 64 and 66 is adhered to for the reasons discussed above.

7. Claims 54 and 56 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- In Claims 54 and 56 is recited the limitation "wherein agent has activity against insects of two or more orders selected from Lepidoptera, Coleoptera; Homoptera". There is insufficient antecedent basis for this limitation in said claims because Claims 53 and 55 from which Claims 54 and 56 respectively depend are dependent on Claim 3. Said limitation is not recited in Claim 3.

### ***Claim Rejections – 35 U.S.C. §§ 102(b)/103(a)***

8. Claims 3, 53-56 and 63-66 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Jarrett et al. (WO 98/08388) in light of Ensign et al (WO 98/50427).

Citing Case laws, applicants argue that above cited rejection is "plainly improper" because Jarrett et al. fail to disclose the claimed invention either expressly or inherently. Applicants further argue that presently claimed invention is neither anticipated nor obvious over Jarrett et al., because instantly claimed invention teaches to obtain said insecticidal agent from a bacterium (i.e., *Xenorhabdus bovienii*) that is completely different than that (i.e., *Xenorhabdus nematophilus*) taught in teachings from Jarrett et al. because each one of those bacteria have a different 16s rRNA pattern and said insecticidal protein from each one of those bacterial species have a different host range.

In response to applicants' above arguments regarding the rejections to Claims 3, 53-56 and 63-66, said claims still remain anticipated and obvious over the Examiner-cited prior art reference because applicants have only demonstrated that the two organisms are taxonomically different. Applicants, however, have not demonstrated that the insecticidal proteins obtained from each one of those two bacteria (i.e., *X. bovienii* and *X. nematophilus*) possess different insecticidal activity, because applicants have not conducted a parallel test against each one of the insects that the prior art reference cites. Furthermore, the insecticidal proteins from each one of bacteria (i.e., *X. bovienii* and *X. nematophilus*) have demonstrated insecticidal activity against same insect species (e.g., *Pieris brassicae* and *Plutella xylostella*). The fact that the two organisms (i.e., *X. bovienii* and *X. nematophilus*) have same

physiological and biochemical characteristics and the insecticidal protein obtained from each one of the organisms has demonstrated insecticidal activity toward same insects makes applicants' invention anticipatory and obvious over the examiner cited prior art reference (i.e., Jarrett et al.), because Examiner has cited Ensign et al. reference to support Jarrett et al's teachings and to merely to make the point that insecticidal agent from *Xenorhabdus* strains have insecticidal activity over Lepidopteran and Coleopteran insects.

With regard to applicants' argument regarding applicants' invention not being inherently anticipated by Jarrett et al., Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results in** the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

Jarrett et al. Clearly teach an insecticidal activity from a bacterial strain that possesses same biochemical and physiological characteristics as the instantly claimed bacterial species and further the protein from prior art reference bacterium has insecticidal activity against the same insects as recited in the instantly claimed invention. Thus, Jarrett et al's teachings meet the first criterion for inherency that of same result as claimed in instant invention. By default the second criterion for inherency is always present. The third criterion for inherency- missing descriptive material would be clear to an artisan of ordinary skill because the steps and end result in Jarrett et al's teachings are same as those in instantly claimed invention. Thus, in absence of any evidence to contrary, the instant claimed invention is anticipated by, and is obvious over examiner-cited prior art.

Applicant's arguments filed July 15, 2003 as Paper Number 10 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. §§ 102(b)/103(a) is adhered to for the reasons of record and the additional reasons discussed above.

### CONCLUSION

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No Claims are allowed.

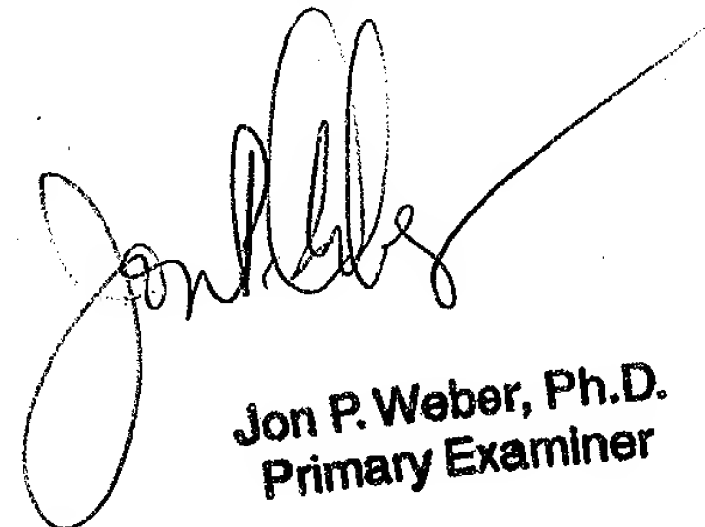
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Daylight Saving, or Standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9306.

Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(703) 605-1196

October 7, 2003



Jon P. Weber, Ph.D.  
Primary Examiner